UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation *This Document Relates to All Actions*	Case No. 19-md-02875 (RBK/KW)

PLAINTIFFS' REQUESTS FOR PRODUCTION OF DOCUMENTS TO ALL API AND FINISHED-DOSE MANUFACTURING DEFENDANTS REGARDING LOSARTAN AND IRBESARTAN ECONOMIC LOSS CLAIMS:

TO ALL DEFENDANTS AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that pursuant to Federal Rule of Civil Procedure 34 and Local Civil Rule 34.1[1], Plaintiffs propound the following discovery requests upon each API and finished dose-manufacturing defendant:[2]

[1] To the extent it applies, these requests are also made pursuant to the Court's rulings at oral argument on December 11, 2019 and December 18, 2019, and in the Order dated December 13, 2019, as well as the Court's Order on macro discovery issues med on November 25, 2019.

[2] Each request is to be interpreted, to the extent it applies, consistent with the Court's oral rulings at the November 20, 2019 hearing on macro discovery issues: The Court's November 25, 2019 Order on macro discovery issues (Dkt. 303); the parties' representations as reflected in the record of the December 11, 2019 discovery hearing; and the Court's oral rulings at the December 11, 2019 discovery hearing.

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DEFINITIONS

"Active Pharmaceutical Ingredient" ("API") is defined as any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance. 21 C.F.R. § 207.1; see also 21 C.F.R. § 314.3.

"API Manufacturer" is defined as any entity identified as a Defendant in Plaintiffs' Master Complaints that manufactures the active pharmaceutical ingredient (API) for losartan or irbesartan.

"Finished Dose Manufacturer" includes any entity identified as a Defendant in Plaintiffs' Master Complaints that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of losartan or irbesartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

"Manufacturer Defendants" includes API Manufacturers and Finished Dose Manufacturers including any subsidiaries or affiliated entities.

"Communication(s)" means the transmittal of information, in the form of facts, ideas, inquiries, documents or otherwise, and includes all transmissions of information received or transmitted by you, including correspondence, regardless of whether you are an author or addressee of such transmittal.

"Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation (including attachments to mails), whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof.

This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form). Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database. For purposes of these discovery requests, "Documents" shall refer only to centrally stored,

noncustodial data maintained by the retailer pharmacy in the ordinary course of business and available via reasonable search of available records and in a reasonably accessible format, and shall not refer to documents or data maintained solely by individual stores or pharmacies, or to emails or custodial data held by individual employees of the Retail Pharmacy Defendants.

Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is January 1, 2011 through December 31, 2019. (If a Defendant is aware that the time period should extend beyond December 31, 2019 please confirm the appropriate date and basis therefor).

"Retail Pharmacy Defendants" refers to any and all entities listed by name as "Retail Pharmacy Defendants" in Plaintiffs' Master Complaints, including any agents or predecessor entities.

"TPP" refers to Third Party Payors, including health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third party payors, and any other health benefit provider in the United States of America and its territories.

"Losartan" or "LCDs" means any drug with losartan as an active ingredient. For purposes of these Requests, "Losartan" or "LCDs" is limited to only those drugs with a National Drug Code (NDC) associated with any of the Manufacturer Defendants identified in Plaintiffs' Master Complaints.

"Irbesartan" or "ICDs" means any drug with irbesartan as an active ingredient. For purposes of these Requests, "Irbesartan" or "ICDs" is limited to only those drugs with a National Drug Code (NDC) associated with any of the Manufacturer Defendants identified in Plaintiffs' Master Complaints.

"Recalled Product" means any drug with losartan or irbesartan as an active ingredient, as well as all finished drug formulations of losartan or irbesartan, including any losartan-containing drug or irbesartan-containing drug, that was subject to a voluntary or mandatory recall, to the extent identifiable from Documents kept by the Retail Pharmacy Defendant(s) in the ordinary course of business.

"You," "your" or "defendant" shall be used interchangeably and refers to the parties to which these requests are directed.

"Drug Supply Chain Security Act" refers to Pub. L. 113-54 and regulations promulgated thereunder.

"Wholesaler Defendants" refers to Amerisource Bergen Corporation, Cardinal Health, Inc., or McKesson Corporation, as identified in Plaintiffs' Master Complaints, including any agents, employees, or predecessor entities, to the extent known to the Retail Pharmacy Defendants.

DOCUMENTS TO BE PRODUCED:[3]

I. CORPORATE ORGANIZATION

1. To the extent not already provided, produce organizational charts setting forth the corporate organization for each named defendant, from January 2011 to the present as follows:

    a. General corporate organizational charts for each defendant, including any affiliated entities involved in the manufacture, testing, distribution, or sale of Irbesartan or Losartan;

    b. Medical affairs/ clinical affairs department, or the equivalent;

    c. Quality assurance department, or the equivalent;

    d. Manufacturing department, including any departments involved in the manufacturing process for Irbesartan or Losartan;

    e. Procurement department;

    f. Sales department;

    g. Marketing department;

    h. Research and development department;

    i. Department(s) responsible for designing, funding, or supervising clinical trials (including all Phase I, II, III, and IV);

    j. Regulatory department;

    k. Department responsible for epidemiology and/ or statistical analysis;

    l. Department responsible for providing professional education to physicians;

[3] To the extent the response to any request would duplicate the response and production already provided in connection with the Valsartan productions, You may indicate this information on an item by item basis, with reference to the specific Bates numbers of previously produced documents.

m. Department(s) responsible for establishing or maintaining relationships involving Losartan, with any other defendant named in this MDL

2. To the extent not already provided, produce organizational charts or similar documents setting forth:

    a. All corporate officers;

    b. All members of the Board of Directors;

3. To the extent you have conducted business relating to the manufacture, testing, distribution, sale, or marketing of Losartan or Irbesartan with any other defendant in the above-captioned MDL, produce all relevant documents, including contracts, invoices, payment records, records related to testing, quality, and purity, and communications, demonstrating the nature, extent, and length of this business relationship.

II. RELEVANT CUSTODIANS

4. Produce documents identifying the corporate employees or retained third parties responsible for or involved in the (1) manufacture, (2) testing, (3) quality assurance, (4) risk assessment, (5) medical and clinical assessments, (6) regulatory activities, (7) communications with regulatory agencies, (8) distribution, (9) production, (10) packaging, (11) sale, (12) marketing, and (13) communications with private individuals or entities regarding safety, therapeutic and pharmaceutical equivalence, purity, contamination, and pricing, with regard to Losartan and Irbesartan.

III. POLICIES AND PROCEDURES

5. Produce all final versions of policies, procedures, standard operating procedures, or protocols for or relevant to the (1) manufacture, (2) testing, (3) quality assurance, (4) risk assessment, (5) medical and clinical assessments, (6) regulatory activities, (7) communications with regulatory agencies, (8) production, (9) distribution, (10) packaging, (11) sale, (12) marketing, and (13) communications with private individuals or entities, regarding safety, therapeutic and pharmaceutical equivalence, purity, contamination, and pricing, with regard to Losartan and Irbesartan, and/or the ingredients thereof. In addition, provide all indexes or lists of the requested documents.

IV. AGREEMENTS

6. Produce all agreements, contracts, or licenses that the answering defendant is a party to, with regard to (1) the manufacturing process, (2) testing for therapeutic and pharmaceutical equivalence, identity, quality, purity, or contamination, (3) quality assurance, (4) risk assessment, (5) medical and clinical assessments of therapeutic and pharmaceutical equivalence, identity, quality, purity, or contamination, (6) regulatory activities, (7) communications with regulatory agencies, (8) production, (9) distribution, (10) packaging, (11) sale, (12) marketing, (13) communications with private individuals or entities, regarding safety, therapeutic and pharmaceutical equivalence, identity, quality, purity, contamination, and pricing, and (14) procurement of components or ingredients, with regard to Losartan and Irbesartan and or their ingredients.
7. Produce all agreements, memoranda, and payment or expense records, with regard to any attempt by defendant to retain, engage or otherwise provide financial support or item of

value to any person or entity with regard to proposed or actual scientific, toxicological, or medical study of Losartan or Irbesartan.

8. Produce all agreements to engage any third party to represent your interests before the FDA or any regulator authority, with regard to Losartan or Irbesartan.

9. Produce all agreements with regard to the retention of persons in any medical or scientific discipline to study, assess or analyze the safety, quality, purity, or contamination of Losartan or Irbesartan for or on behalf of any defendant.

10. Produce all agreements, memoranda, and payment or expense records, with regard to providing funds or anything of value to any person who spoke at or attended any conference for the purpose of increasing the distribution of Losartan/Irbesartan.

V. INTRA-DEFENDANT COMMUNICATIONS

11. All communications between or among any of the defendants with regard to (1) the manufacturing process, (2) testing capable of indicating quality, identity, purity, therapeutic or pharmaceutical equivalence, or contamination, (3) quality assurance related to quality, identity, purity, therapeutic or pharmaceutical equivalence, or contamination, (4) risk assessment with regard to quality, purity, contamination, and/or the use of solvents, (5) medical and clinical assessments of risks related to quality, identity, purity, therapeutic or pharmaceutical equivalence, or nitrosamine contamination, (6) communications with regulatory agencies regarding quality, identity, purity, therapeutic or pharmaceutical equivalence, or contamination , (7) terms or conditions of distribution, (8) sale and price numbers at all levels of the supply chain, (9) pricing at all levels of the supply chain, and (10) procurement or use of solvents, with regard to Losartan or Irbesartan.

VI. ANDA AND DMF

12. To the extent any ANDA file for Losartan or Irbesartan sold in the United States was not produced in whole or in part during Core Discovery, produce the entire file.
13. Produce all correspondence with the FDA concerning any ANDA for Losartan and Irbesartan sold in the United States, whether or not ultimately approved, including prior to and after the relevant time period identified herein.
14. Produce all documents containing the list of ingredients and synthesis processes to manufacture Losartan and Irbesartan sold in the United States, beginning from the date you first began development of the process for manufacturing the API for Losartan or Irbesartan sold in the United States.
15. Produce all documents relating to Abbreviated New Drug Applications (ANDAs) filed by you with regard to Losartan sold in the United States, beginning from the date you first began development of the process for manufacturing the API for Losartan or Irbesartan sold in the United States
16. Produce all complete drug master files for Losartan or Irbesartan sold in the United States, including supplements, revisions, and modifications, to the extent not produced to date, and all documentation of communications with any person or entity with regard to all versions and revisions of the drug master files for Losartan and Irbesartan sold in the United States.

VII. MANUFACTURING

17. Produce all documents with regard to the manufacturing process for the active pharmaceutical ingredient in Losartan and Irbesartan, including any modifications thereto.

18. Produce all documents with regard to the machines, materials, and substances (including but not limited to new or recycled solvents, tainted or contaminated solvents) utilized in the manufacturing process for the active pharmaceutical ingredient in Losartan and Irbesartan, including specifications, manuals, material safety data sheets, machine settings and calibrations, and any modifications thereto.[4]

19. Produce all documents (including photographs or video) with regard to any testing or inspections of Losartan and Irbesartan for quality, purity or contamination.[5]

20. Produce all documents setting forth the manufacturing/fabrication/production process for the finished drug formulation of Losartan and Irbesartan sold by you or any of your affiliated entities, including any quality assurance and testing, and any modifications thereto.[6]

21. Produce documentation demonstrating the name, address, and role of any third party which supplied you with Losartan or Irbesartan or any ingredient, material, or component used in the manufacture of Losartan or Irbesartan, and any evaluation or testing thereof. For finished dose manufacturers this request is limited to the supply to you of Losartan and Irbesartan API.

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[4] To the extent it applies this request should be interpreted consistent with the record during the December 11, 2019 Court hearing.

[5] To the extent it applies, the scope of relevant testing should be consistent with that set forth in paragraph 8 of the Court's ruling on macro discovery issues (Dkt. 303). As stated in the Court's November 25, 2019 Order, this includes tests showing unknown and unidentified testing peaks or general toxic impurities in the API or drug itself, any test that could identity the presence of nitrosamine contamination, and testing and results regarding other carcinogens, general toxic impurities, or residual solvents in the API and drug. As ordered during the December 11 Court hearing, the relevant time period for production shall date back to the start of the implementation of the manufacturing process.

[6] To the extent it applies this request should be interpreted consistent with the record during the December 11, 2019 Court hearing.

22. Produce all certificates of analysis or similar documents concerning analysis of the quality, purity or contents of Losartan and Irbesartan, including the catalysts and solvents used in the tetrazole ring process, and Documents and Communications concerning the same,
23. Produce documentation identifying (1) each lot, batch, or other production quantity of Losartan and Irbesartan manufactured, purchased, or sold by defendant (including discarded or recalled lots or batches), (2) the dates of manufacture for each, (3) the solvent(s) (including residual or reused solvents) utilized in the manufacture of each, and (4) any information you obtained with regard to potential risks of the use of any solvent or chemical utilized, including residual or reused solvents, (5) Certificates of Analysis and Material Safety Data Sheets, and any other documents provided by any manufacturer or supplier with regard to the solvents, chemicals, and other substances utilized in each of the manufacturing processes for each, and (6) any evaluation, analysis, or consideration of the contents of the Certificates of Analysis and Material Safety Data Sheets, and any other documents provided by any manufacturer or supplier with regard to the solvents, chemicals, and other substances utilized in each of the manufacturing processes for each, including any impurities listed therein.
24. Produce documentation of all scientific journal articles submitted to any academic or scientific publication, written or drafted in whole, or in part, by your employees or scientists or third parties who received funding or other forms of compensation from you, regarding the manufacturing of Losartan and Irbesartan, including the final version, any drafts, edits, and peer reviewed feedback.
25. All communications and documents exchanged between you and any third party, regarding the manufacturing process associated with the creation of Losartan and Irbesartan,

including but not limited to the use of solvents, the tetrazole ring formation process, testing, and quality, purity, and contamination issues.

VII. THERAPEUTIC AND PHARMACEUTICAL EQUIVALENCE

26. All documentation of the therapeutic and pharmaceutical equivalence of any Losartan or Irbesartan sold or manufactured (in whole or in part) by you, to the Reference Listed Drug ("RLD"), including but not limited to, testing, communications with the FDA, communications with customers, suppliers, or other third parties, and certifications of therapeutic and pharmaceutical equivalence.
27. All marketing materials referencing the therapeutic and pharmaceutical equivalence of Losartan or Irbesartan manufactured, distributed, or marketed by you.
28. All documents and communications regarding the identification by any person or entity of any Losartan or Irbesartan manufactured, utilized, or sold by or to you as not being therapeutic and pharmaceutical equivalents to the RLD.
29. All documents and communications relevant to Losartan or Irbesartan entries in the FDA's "Orange Book."

VIII. TESTING

30. Produce all documents setting forth or addressing the results of any testing (including chromatography) of Losartan or Irbesartan that had the potential to directly or indirectly identify impurities or contamination.

31. Produce all documentation with regard to the first test that indicated impurity or contamination of Losartan or Irbesartan that was potentially due to a nitrosamine, whether or not identified as nitrosamine impurity or contamination at the time.
32. Produce all documentation with regard to each notification to You of any impurity or contamination of Losartan or Irbesartan that was, or potentially was, due to a nitrosamine, whether or not identified as nitrosamine contamination at the time. In connection with this request, separately identify the first such notification.
33. Produce all documents with regard to evaluation by an employee of defendant or a third party, with regard to the health risks of Losartan or Irbesartan nitrosamine contamination.
34. Produce documentation of all studies of the ingredients, impurities, and actual or potential nitrosamine contamination, of Losartan or Irbesartan conducted by any third parties, including, but not limited to, those conducted by Contract Research Organizations (CRO), educational institutions, publicly or independently funded groups, competitors, trade groups or associations, regulatory entities, irrespective of whether such studies were conducted at the direction of Defendant.
35. Produce documentation of any report or analysis made known to Defendant with regard to the relationship between the use of contaminated Losartan or Irbesartan and potential or confirmed injuries; and the review of same by any employee or consultant of Defendant.
36. Provide documentation of the results of any clinical or animal study regarding Losartan or Irbesartan conducted with potentially contaminated Losartan or Irbesartan during the relevant time period, whether or not sponsored by, financed by, undertaken by, or suggested by Defendant, and any internal analysis thereof.

37. Produce complete documentation of (a) all testing relevant to determination of quality, purity, therapeutic and pharmaceutical equivalence, or contamination, prior to any recall, of Losartan or Irbesartan you manufactured or sourced, (b) all testing relevant to a determination of quality, purity, therapeutic and pharmaceutical equivalence, or contamination after any recall, of Losartan or Irbesartan you manufactured or sourced, (c) the results of the foregoing testing; (d) any such testing that was considered but not performed before or after any recall, including the reason(s) why such testing was not performed, and (e) to the extent any lot, batch, or other production quantity was not tested for impurities, therapeutic and pharmaceutical equivalence, or contamination, complete documentation with regard to the reason(s) why no such testing was performed.
38. Produce complete documentation of all testing referenced in paragraph number 40 above that was begun but not completed, and all documents showing the contact information for the individuals involved.

IX. NITROSAMINES AND CONTAMINATION

39. Produce complete documentation identifying each lot, batch, or other production quantity of Losartan or Irbesartan, (a) confirmed to be contaminated and the quantification of the contamination; (b) assumed to have been contaminated and the quantification of the contamination; (c) confirmed not to be contaminated; (d) assumed not to be contaminated, and (e) confirmed or assumed to be contaminated.
40. Produce complete documentation of any testing for any nitrosamine, including but not limited to NDMA, NDEA, NMBA, and any other nitrosamine or carcinogenic contaminant

in Losartan or Irbesartan, or any other API or finished drug manufactured, formulated, distributed, or sold by the answering defendant.

41. Produce complete documentation of any testing or research conducted by you or a third party on your behalf to determine the existence or quantification of nitrosamine contamination in any Losartan or Irbesartan API or finished drug formulation.

42. Produce complete documentation for any root cause analysis for nitrosamine contamination in any Losartan/Irbesartan API or Losartan/Irbesartan product.

43. Produce complete documentation with regard to the analysis of health risks due to contamination of Losartan or Irbesartan with any nitrosamine or other carcinogenic substance, conducted by you or any third party on your behalf.

44. Produce all studies, data, or other scientific or medical information reviewed or considered by any employee or third party on your behalf with regard to the health risks due to contamination of Losartan or Irbesartan with any nitrosamine or other carcinogenic substance.

45. Produce all formal or informal reports or complaints by or to Defendant or any other person or entity to your knowledge, with regard to Losartan or Irbesartan nitrosamine contamination.

46. Produce all documents known to you, embodying any analysis or opinion by any person or entity, regarding the potential health risks of nitrosamine contamination of Losartan or Irbesartan.

X. REGULATORY CORRESPONDENCE AND DOCUMENTS

47. Produce all regulatory documentation and communications with regard to contamination or recalls of Losartan or Irbesartan.[7]

48. Produce all regulatory documentation and communications with regard to the use of solvents, solvent recovery, solvent recovery vendors, tetrazole ring formation, and potential impurities or contamination in connection with the manufacturing process for Losartan or Irbesartan.[8]

49. Produce transcripts, notes, memoranda, or other documentation of any hearings or other proceedings or meetings which took place at or with any regulatory agency relating to the actual and/ or potential contamination or recall of Losartan or Irbesartan.[9]

50. Produce all documents with regard to any FDA Advisory Panel meetings regarding Losartan or Irbesartan contamination.

51. Produce all Establishment Inspection Reports (including foreign Regulatory equivalents of Establishment Inspection Reports) and related documentation (including photographs or video) concerning your facilities or the facilities of any other defendant used in the manufacture, fabrication, packaging, distribution, or sale of Losartan or Irbesartan.[10]

52. Produce all documents relating, referring to or embodying all inspection reports (including 483s, detention reports, warning letters, or consent decrees, including foreign Regulatory equivalents) which pertain in any way to Losartan or Irbesartan contamination or any facility in which contaminated Losartan or Irbesartan was manufactured.[11]

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[7] To the extent it applies, as limited by the Court's Order.
[8] To the extent it applies, as limited by the Court's Order on macro discovery issues (Dkt. 303).
[9] To the extent it applies, as limited by the Court's Order on macro discovery issues (Dkt. 303).
[10] To the extent it applies, as limited by the Court's Order on macro discovery issues (Dkt. 303).
[11] To the extent it applies, as limited by the Court's Order on macro discovery issues (Dkt. 303).

53. Produce complete documentation regarding any CAPAs (Corrective and Preventative Actions) relating to the manufacture of Losartan or Irbesartan, including documentation showing what caused the CAPA to be opened and/or closed.[12]

54. Produce all documentation, and related communications, of any complaints or third-party communications to or from any regulatory agency with regard to actual or potential Losartan or Irbesartan contamination.[13]

55. Produce all documentation, including source files, for any MAUDE or other adverse event reports submitted to any regulatory agency with regard to cancer, or any injury potentially caused by Losartan or Irbesartan contamination, and any related communications.[14]

56. Produce complete files for all formal or informal adverse event reports and/or MedWatch reports concerning cancer, or any injury potentially caused by Losartan or Irbesartan contamination, including: a) causation analyses, b) summaries (including, but not limited to, computerized data), analysis or interpretations of any such adverse event report(s) (including any post-marketing submissions); and c) documents which discuss or refer to any adverse event report, or any summary, analysis or interpretation thereof.[15]

57. Produce all databases maintained by you concerning both domestic and international formal and informal adverse event reports and/or MedWatch reports, including the underlying medical information and raw data maintained by you, with regard to reports of cancer, or any injury potentially caused by contaminated Losartan or Irbesartan.[16]

[12] To the extent it applies, as limited by the Court's Order on macro discovery issues (Dkt. 303).
[13] To the extent it applies, as limited by the Court's Order on macro discovery issues (Dkt. 303).
[14] To the extent it applies, as limited by the Court's Order on macro discovery issues (Dkt. 303).
[15] To the extent it applies, as limited by the Court's Order on macro discovery issues (Dkt. 303).
[16] To the extent it applies, as limited by the Court's Order on macro discovery issues (Dkt. 303).

58. Produce all filings with the Securities and Exchange Commission (SEC), addressing the sale of contaminated Losartan or Irbesartan, including Forms 10-K, 10-Q, 8-K, and proxy statement (Schedule 14A), whether such filings are tentative, final, definitive, or supplemental.

59. Produce complete documentation of any communications with any state Regulatory or health authorities regarding Losartan or Irbesartan quality, purity, therapeutic or pharmaceutical equivalence, contamination, or pricing.[17]

60. Produce complete documentation of Defendant's efforts to comply with Current Good Manufacturing Practices (cGMPs), and any actions or inactions that did not meet or might not have met cGMPs, with regard to the Losartan or Irbesartan manufacturing process and use or reuse of solvents in the Losartan or Irbesartan manufacturing process, including, but not limited to, documents identifying any cGMP consultants retained by Defendant, documents regarding cGMP compliance provided to the FDA, and responses to FDA 483s and Warning Letters regarding cGMP compliance.[18]

XI. COMPLAINTS AND RECALLS

61. Produce complete documentation with regard to each implementation of a recall due to contamination of Losartan or Irbesartan.

62. Produce all final recall notices with regard to contamination of Losartan or Irbesartan.

[17] To the extent it applies, as limited by the Court's Order on macro discovery issues (Dkt. 303).
[18] To the extent it applies, as limited by the Court's Order on macro discovery issues (Dkt. 303).

63. Produce all documents setting forth or addressing any communications with any customer or consumer relating to the recall (or non-recall) of Losartan or Irbesartan due to contamination.

64. Produce all communications directly with physicians relating to the recall (or non-recall) of Losartan or Irbesartan due to contamination.

65. Produce all communications with any person or entity to which, or from which, you purchased or sold Losartan or Irbesartan, with regard to Losartan or Irbesartan contamination.

66. Produce all documents and communications with regard to the scope of any recall considered or implemented with regard to Losartan or Irbesartan contamination.

67. Produce all documents and communications with regard to any complaint or concern raised by any person or entity relating to the purity, bioequivalence, or contamination of Losartan or Irbesartan.

68. Produce all documents or communications concerning any actual or potential import or export alerts relating to Losartan or Irbesartan contamination.

69. Produce all documents and communications concerning any buybacks or refunds that you paid to any purchasers of Losartan or Irbesartan in the United States related to Losartan or Irbesartan contamination.

70. Produce all communications (and drafts) to or from Defendant regarding recalls of Losartan or Irbesartan related to Losartan or Irbesartan contamination, including lists sufficient to show all persons or entities who received communications.

71. Produce documents sufficient to identify any person or entity retained by Defendant with regard to the recall of Losartan or Irbesartan due to nitrosamine contamination.

XII. WARRANTIES AND STATEMENTS

72. Produce all versions of defendant's labeling, package inserts, patient leaflets, and medication guides for Losartan or Irbesartan in the United States, together with a chart of the approval dates and in use dates for all versions that were utilized in the sale and marketing of Losartan or Irbesartan.

73. Produce all statements regarding purity, quality, compendial status, therapeutic equivalence, pharmaceutical equivalence, and contamination provided to medical professionals, purchasers including TIPs, consumers, wholesale distributors, retail pharmacies, and other direct and indirect purchasers of Losartan or Irbesartan, for each NDC, Batch Number, and Lot Number of Losartan or Irbesartan sold in the United States during the relevant time period.

74. Produce all communications between you and any medical professional or medical association concerning the risk of cancer, associated with Losartan or Irbesartan nitrosamine contamination.

75. Produce all communications with healthcare providers regarding quality, compendial status, therapeutic equivalence, pharmaceutical equivalence, contamination, or recall status, of Losartan or Irbesartan.

76. Produce all public statements (and drafts) issued by Defendant regarding Losartan or Irbesartan quality, purity, compendial status, therapeutic equivalence, pharmaceutical equivalence, and contamination.

77. Produce all communications with the Centers for Disease Control (CDC), National Institutes of Health, World Health Organization, U.S. Drug Enforcement Agency, U.S.

Department of Justice, U.S. Attorney General, any regulatory agency, or any state agency, relating to Losartan or Irbesartan contamination.

78. Produce all documents relating to any investigative subpoenas and subsequent investigation from the United States Department of Justice, United States Congress, and/or any other federal or state entity, relating to Losartan or Irbesartan contamination.

79. Produce all documents relating to, referring to or embodying any discussion or submission between defendant and any state government regulatory agency or any state medical society concerning reimbursement for Losartan or Irbesartan purchases.

XIII. SALE AND DISTRIBUTION

80. Produce complete documentation setting forth and/or demonstrating the complete supply and distribution chain for Losartan or Irbesartan purchased, sold, or distributed by you, from the manufacture of the API through the final sale to the consumer.

81. Produce all documents relating to the sale and distribution of Losartan or Irbesartan that reflect NDC, batch number, and lot number.

82. Produce documents sufficient to show all sales of Losartan or Irbesartan to finished dose manufacturers, wholesalers, distributors, retailers, and consumers, including the total net sales, total number of pills and/ or units sold, unit price, unit cost, profit margin, and market share by state or territory.

83. Produce all documentation relating to the due diligence performed in selecting an API or finished dose manufacturer from which you purchased Losartan or Irbesartan, including but not limited to policies and standard operating procedures.

84. Produce all communications received from any API manufacturer or finished dose manufacturer with regard to the manufacturing process, purity, quality, compendial status, therapeutic equivalence, pharmaceutical equivalence, or contamination, relating to Losartan or Irbesartan.

85. Produce complete documentation of the basis for Defendant's decision to purchase Losartan or Irbesartan from any API or finished dose manufacturer, including documents you reviewed or relied on to make those decisions.

86. Produce documents sufficient to show the number of losartan or irbesartan pills sold by you and to whom each pill was sold, at what price, and on what terms.

87. Produce documents sufficient to show the total number of pills that were sold or distributed to consumers, at what price, and how many pills were recovered or returned as a result of the recall.

XIV. IDENTIFICATION OF PURCHASERS

88. Produce documents sufficient to identify all persons and entities (including consumers and TPP entities) who purchased, reimbursed, or paid or otherwise compensated you for Losartan or Irbesartan you manufactured, sold or distributed in the United States. If available, produce documents sufficient to show these individuals' or entities' names, last known mailing addresses and email addresses, last known telephone numbers, date(s) of purchase, NDC Code(s), Batch Number(s), and Lot Numbers.

89. Produce all communications between or among you and any named plaintiff acting as a class representative, or putative class representative, including the named consumer representatives and/or named TPP representatives, with regard to Losartan or Irbesartan.

XV. SALES AND PRICING

90. Produce documents sufficient to show (i) the customers to whom you sold Losartan or Irbesartan API or Losartan or Irbesartan finished dose, (ii) unique identifiers for product sold (e.g., lot number, batch number, NDC code, etc.), (iii) quantities of Losartan or Irbesartan API or Losartan or Irbesartan finished dose sold, (iv) dates of sale, and (v) net and gross price per sale. The parties will meet and confer about the scope and form of data based on the particular data maintained by each Defendant and thereafter to determine the extent to which additional information will be needed including information required for class certification.

XVI. AVAILABLE DATA SOURCES

91. Produce all documents relating to all IMS, Verispan, MediSpan, Scott-Levin, Price Check, ImpactRx, First DataBank, IQVIA, or other pharmaceutical industry data products purchased and or subscribed to or available to you regarding Losartan or Irbesartan.

92. Produce all data or reports generated by IMS, CMS, or Verispan, IQVIA, or any comparable third party person or entity (including, but not limited to, Medi-Span, ImpactRx, and First DataBank), in whatever format it was received, relating to the sale, pricing, prescription, marketing, promotion, or detailing of Losartan or Irbesartan from date of launch to the present for Losartan or Irbesartan, including:

    a. IMS National Prescription Audit data, including TRx, NRx, extended units, retail sales dollars and retail sales price. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.

b. IMS National Sales Perspective data, including total units, extended units, total sales dollars, and price. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.

c. CMS national Health Expenditures and Drug Utilization data, including TRx, NRx, Medicaid percentage paid, extended units, retail sales dollars, and retail sales price, with regard to Losartan.

d. Verispan Vector One National (VONA) data, including TRx, NRx, extended units, retail sales dollars, and retail sales price, with regard to Losartan. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.

e. IQVIA data, including for sale quantities, and sale prices.

93. Produce all documents relating to any coupon or co-pay assistance you made available to consumers for Losartan or Irbesartan.

Dated: May 22, 2023

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CERTIFICATE OF SERVICE

I certify that on the 22nd day of May 2023, I electronically transmitted the attached document to counsel of record in the above-captioned case.

/s/ Marlene J. Goldenberg
Marlene J. Goldenberg